

REMARKS

Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 were pending in the application and were rejected. Claims 1, 4, 5, 7, 16, 21, 30, 33, 35 and 42 have been amended and claims 48 and 49 are new. None of the amended or new claims introduce new subject matter. Amended claims 4 and 42 are supported at page 5, lines 24-27. Amended claim 16 is supported at page 16, lines 14-17. Amended claims 1, 33, 35 and 42 add no new matter and provide changes of grammatical form. Amended claims 1, 33, 35 and 42 and new claim 48 are supported at page 4, lines 19-21, page 5, lines 17-18 and page 16, lines 4-10. New claim 49 is supported by original claim 35.

The amendment to the specification is supported by original claim 17.

Double Patenting

Applicant acknowledges that a provisional double patenting rejection has been made of the pending claims in this application over claims 1, and 3-50 of copending Application No. 10/376,736. However, since neither the claims of the present application nor the copending application have yet been finalized, Applicant is unable to respond at this time. Applicant reserves the right to rebut the provisional rejection, at such time as these claims are otherwise in condition for allowance and a rational comparison of the two sets of claims can be made.

35 USC §112

Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 were rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The examiner objected that the claim amendments introduce new matter. Applicant traverses the rejection.

The Examiner stated that a previous amendment of claim 1 which recites that “the polymeric matrix layer dissolves or disintegrates in the presence of water” is new matter. The Examiner further stated “Nowhere in the originally filed specification applicants disclosed that ‘the polymer matrix layer dissolves or disintegrates in the presence of water’.” Applicant disagrees. The specification states at page 4, lines 19-20 that the patch comprises a bioadhesive *water soluble* polymeric matrix. At page 4, lines 23-27, the specification discloses that the

characteristics of the patch include natural dissolution of the patch at the delivery site. At page 5, lines 11-19, the specification explains that the dissolution rate *of the patch* in water can be adjusted by selection of polymers used in the patch. The definition of *water* soluble is that it dissolves in water. Thus, the specification discloses that the polymeric matrix layer patch dissolves in water and that there is dissolution of the patch in water. It is not required that the claims be supported by the identical words in the specification, e.g., a drawing can support a claim. (MPEP 2163.02) Case rulings state the rule explicitly. *In re Edwards, Rice and Sonlen*, 196 USPQ 465, 467 (CCPA 1978) ("To comply with the description requirement, it is not necessary that the application describes the claimed invention *in ipsis verbis*"). Since the specification states that there is dissolution of the patch, and since an appropriate verb to express "dissolution" is "disintegrate," the claims are supported by the specification. (Exhibit 1, Webster's II New College Dictionary, definition of dissolution).

The Examiner stated that the previous amendment, which recites that "the patch is configured as a film for application to the skin," is new matter. Applicant disagrees. The amendment to the claims is supported throughout the specification although the claims do not repeat the specification *in ipsis verbis*. The claimed invention is a patch consisting of a single polymeric matrix layer and at page 14, lines 16-19 the specification discloses *dyeing the film layer* of the patch. Page 8, lines 17-20 discloses that when the patch comprises vegetable preparations, the vegetable preparations can also be released from *the film layer*. Example 2, at pages 19-20 describes a patch that has a thickness of 150 microns. Likewise, examples 3-7 describe a patch of 150 microns in thickness, cut into a circular shape prior to application to the skin. Those specifications (150 microns) meet the recitation of a patch that is configured as a film for application to the skin.

For all the above reasons, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to distinctly claim the subject matter. Applicant traverses the rejections.

Independent claim 35 should not have been included in this rejection because the claim does not contain the expressions that were deemed by the Examiner to be indefinite.

As to claims 1, 33 and 42, Applicant has deleted, as unnecessary, the limitations to starch derivatives, modified starch, and modified starch derivatives. Thus the Examiner's rejection of the claims because they contain these terms is moot. Nonetheless, Applicant traverses the Examiner's comment that the specification does not define those expressions in terms of what are the modified starches, derivatives of starch or derivatives of modified starch, that are suitable for practicing the present invention. Numerous examples are provided throughout the specification, such as ¹Instant Textra™, N-Lite® L, and Instant Pure-Cote® B792 (pages 22-24, Example 5) and page 5, lines 24-27.

The Examiner stated that the expression "phenoxy" in claim 7 does not set forth the metes and bounds because the specification does not define the expression. Applicant has deleted the errant comma from claim 7 to correct the expression to "phenoxy isopropanol", supported at page 11, line 19. Applicant has deleted "sorbitol derivatives," which moots the last rejection.

Applicant respectfully requests that the rejections be reconsidered and withdrawn.

35 USC § 102

Claims 1, 4, 5, 13-15, 17, 18, 21, 27, 29-33, 42, and 47 were rejected under 35 USC 102(b) as being anticipated by U.S. Pat. No. 5,780,047 ('047). Applicant traverses the rejection.

Claims 1, 33, and 42, which describe a patch and a method of applying the patch, recite that the patch becomes tacky upon wetting and the adhesive property of the tacky patch adheres the patch to the skin. To the contrary, '047 teaches a patch comprising an adhesive sheet containing an adhesive that enables the patch to be attached to the skin. (Col. 2, lines 53-64). Because it contains an adhesive, the patch of the '027 patent requires a protective sheet to prevent the adhesive patch from sticking to the fingers (Col. 2, lines 39-44). Therefore, '047 does not teach a patch that, upon wetting, becomes tacky to support adhesive application to the skin. US'047 is adhesive at the start due to an adhesive layer rather than becoming tacky and adhesive after wetting. Thus, '047 does not teach every limitation of the claims. For this reason,

independent claims 1, 33 and 42 and all the other claims, which are dependent therefrom, are novel over '047.

Claims 1, 4, 5, 9, 10, 12, 14, 15, 17, 18, 21-24, 27, 29-33, 42, and 47 were rejected under 35 USC 102(e) as being anticipated by U.S. Pat. No. 6,497,887 ('887). Applicant traverses the rejection.

Claims 1, 33, and 42, which describe a patch and a method of applying the patch, recite that the polymeric matrix layer of the patch dissolves in water or disintegrates upon rinsing the patch with water. To the contrary, the '887 membrane cannot dissolve in water or disintegrate because it is formed of cross-linked polymers (Abstract and Col. 2, lines 10-19). When polymers are cross-linked, swelling can occur to form a gel but there is no dissolving into solution. Even lightly cross-linked polymers swell extensively. (See Exhibit 2, Textbook of Polymer Science, page 151, first and third paragraphs). This fact is fundamental to the art of polymer chemistry, as is clear by its inclusion in the Textbook of Polymer Science. US'887 merely describes a dry membrane that is applied to the skin and becomes and remains a swollen gel upon contact with water, remaining in place in gel form as it is rubbed into the skin. US'887 never teaches that the membrane dissolves into water or disintegrates. (Col. 1, lines 58-67; Col. 2, lines 10-19; Col. 2 lines 60-64; Col. 6, lines 58-62). Thus, '887 does not teach each and every limitation of the claims. For this reason, independent claims 1, 33 and 42 and all the other claims that are dependent therefrom, are novel over '887.

In view of all the rebuttal argument presented above, Applicant respectfully requests that all the rejections for anticipation be reconsidered and withdrawn.

35 USC § 103

Claims 7, 8, and 10 were rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. No. 5,780,047 ('047) in view of US 2003/0027833 ('833). Applicant traverses the rejection.

The Examiner conceded that the US '047 does not teach the specific antiseptics and antibiotics recited in claims 7, 8 and 10. The Examiner attempted to cure the defect by combining the teachings of US '047 and US '833. However, as discussed above, and

incorporated herein, US'047 is further defective in failing to teach a patch that becomes tacky after wetting so that the adhesive property of the tacky patch adheres the patch to the skin. US'833 does not cure the defect because it does not teach the missing limitation and furthermore because US'833 teaches two different embodiments that are both defective as to the limitations of the claims. One embodiment is a liquid or gel that forms a film only after application to the body, so this embodiment is outside the limitations of the claims. The other embodiment is multilayered, so this embodiment is outside the limitations of the claims. Since the combination of prior art references the Examiner proposed is nonetheless defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

Claims 7 and 8 were rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,497,887 ('887) in view of US 2003/0027833 ('833). Applicant traverses the rejection.

The Examiner conceded that the US '887 does not teach the specific antiseptics and antibiotics recited in claims 7 and 8. The Examiner attempted to cure the defect by combining US'887 with US'833. However, as discussed above, and incorporated herein, US'887 is further defective in failing to teach the polymeric matrix layer of the patch dissolves in water or disintegrates upon rinsing the patch with water. US'833 does not cure the defect because it does not teach the missing limitation and furthermore because US'833 teaches two different embodiments that are both defective as to the limitations of the claims, as discussed above and incorporated herein. Since the combination of prior art references the Examiner proposed is nonetheless defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over any of U.S. Patent No. 5,780,047 ('047) to Kamiya et al. or U.S. Patent No. 6,497,887 ('887) to Zecchino et al. Similarly claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over US'047

in view of US '887. Similarly claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over US'887 in view of US '047. Applicant traverses the rejections.

The Examiner conceded that neither of the prior art references teach the anti-inflammatory agents recited in claim 11. The Examiner rationalized that since the references disclosed that anti-inflammatory agents are suitable for delivery from the respective compositions, it was within the skill in the art to determine the particular agents in claim 11. The Examiner further conceded that US'047 failed to teach the antihistamine of claim 12 but stated that US'887 teaches the antihistamine. The Examiner further conceded that US'887 failed to teach the menthol or capsaicin of claim 13 but stated that US'047 teaches the menthol or capsaicin. Notwithstanding the Examiner's argument, the various combinations of the two references still fail to disclose every limitation that is incorporated into claims 11, 12 or claim 13. The discussion above of the missing limitations is incorporated herein. Since the combination of prior art references is nonetheless defective in failing to teach a membrane having either (1) the polymeric matrix layer of the patch that dissolves in water or disintegrates upon rinsing the patch with water or (2) a patch that becomes tacky after wetting, so that the adhesive property of the tacky patch adheres the patch to the skin, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

Claims 9, 19, 20, 22-24, 26, 35 and 36 were rejected under 35 USC 103(a) as being unpatentable over US'047 in view of US 2001/0007671 ('671). Applicant traverses the rejection.

The Examiner conceded that US'047 fails to teach the salicylic acid as claimed in claim 9, the transparent polymeric film as claimed in claim 19, the colored film as claimed in claim 20, the cosmetics claimed in claims 22-24, the effervescent claimed in claim 26, or the period of applying the film as claimed in claims 35, and 36. The Examiner attempted to cure the defect by combining the teachings of US '047 and US'671. However, as discussed above, and incorporated herein, US'047 is further defective in failing to teach a patch that becomes tacky after wetting, so that the adhesive property of the tacky patch adheres the patch to the skin. US'833 does not cure the defect because it does not teach the missing limitation. For this reason, alone, no prima facie

showing of obviousness has been presented and the claims are patentable over the prior art.

Furthermore, the Examiner has not presented rational grounds to show that one skilled in the art would have been motivated to combine the teachings of the references. The Examiner stated that one of ordinary skill in the art would have been motivated by the teaching of US'671 that the active ingredients, effervescent or coloring agent when applied topically impart great softness, freshness and coolness to the skin. However, US'671 does not teach that those ingredients impart softness, freshness and coolness. Instead, US'671 teaches that softness, freshness and coolness is imparted by patches with *high water content* and that this also makes the patches easily manipulated during application and removal and that if active agents are incorporated into such patches, these characteristics can be enjoyed during the application of the active agents. (Para. 0007 and 0014). Since the patch of Kamiya does not have high water content, the Examiner's argument has no rational basis and has not provided any showing of motivation to combine the teachings of the references. For this reason alone, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

Claims 19, 20, 26, 35 and 36 were rejected under 35 USC 103(a) as being unpatentable over US'887 in view of US 2001/0007671 ('671). Applicant traverses the rejection.

The Examiner conceded that US'887 fails to teach the transparent polymeric film as claimed in claim 19, the colored film as claimed in claim 20, the effervescent as claimed in claim 26, or the period of applying the film as claimed in claims 35 and 36. The Examiner stated that these are all taught in the patch of US'671. However, as discussed above, and incorporated herein, US'887 is further defective in failing to teach the polymeric matrix layer of the patch dissolves in water or disintegrates upon rinsing the patch with water. US'671 which teaches a patch that is a hydrophilic gelling system that retains water, does not cure the defect. Since the proposed combination does not teach each of the limitations incorporated into these claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

Furthermore, the Examiner has not presented rational grounds to show that one skilled in the art would have been motivated to combine the teachings of the references. The Examiner stated that the elements conceded to be missing from the teachings of US'887 were taught by

US'671 and that one of ordinary skill in the art would have been motivated by the teaching of US'671 that such a film, when applied topically, impart great softness, freshness and coolness to the skin. However, US'671 teaches that softness, freshness and coolness is imparted by patches with *high water content* and that this also makes the patches easily manipulated during application and removal and that if active agents are incorporated into such patches, these characteristics can be enjoyed during the application of the active agents. (Para. 0007 and 0014). Since the gelling quality and high water content is not the aspect of the patch that the Examiner has rationalized to combine with the teachings from US'887, the Examiner has not provided any rational showing of motivation to combine the teachings of the references. For this reason alone, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

Claims 25 and 28 were rejected under 35 USC 103(a) as being unpatentable over any of US'047 or US'887 in view of US 6,419,935 ('935). Applicant traverses the rejection.

The Examiner conceded that US'047 and US'887 fail to teach dihydroxyacetone as in claim 25 or the size of the film as in claim 28. The Examiner stated that US'935 teaches these aspects and that it would have been obvious to combine the teachings of either US'047 or US'887 with that of US'935. Notwithstanding the Examiner's argument, the various combinations of references still fail to disclose every limitation that is incorporated into claims 25 or claim 28. The discussion above of the missing limitations is incorporated herein. Since the combination of prior art references is nonetheless defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

Claims 16 and 38-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over any of U.S. Patent No. 5,780,047 ('047) to Kamiya et al. or U.S. Patent No. 6,497,887 ('887) to Zecchino et al., each in view of U.S. Patent No. 5,667,798 ('798) to Royds et al. Applicant traverses the rejection.

The defects in '047 and '887 have been discussed above and are incorporated herein. The Examiner conceded that those two references failed to teach microencapsulation of active ingredients as recited in claims 16, 38, 39, and 41, or microencapsulation in hydrophobic microcapsules as recited in claim 40. As discussed above and incorporated herein, US'047 is further defective in failing to teach a patch that becomes tacky after wetting, so that the adhesive property of the tacky patch adheres the patch to the skin. US'798 does not cure the defect because it does not teach the missing limitation and in fact teaches an additional layer containing adhesive (Col. 4, lines 47-53). As discussed above and incorporated herein, US'887 is further defective in failing to teach the polymeric matrix layer of the patch dissolves in water or disintegrates upon rinsing the patch with water. US'798 does not teach the missing limitation. Therefore, the combinations the Examiner has proposed fail to teach each of the limitations incorporated into claims 16 and 38-41, so no prima facie showing of obviousness has been made and the claims are patentable over the prior art.

In view of all the rebuttal argument presented above, Applicant respectfully requests that all the rejections for obviousness be reconsidered and withdrawn.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should she believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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